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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/715,556	11/19/2003	Swen Holder	03806.0590-00	5066

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EXAMINER

HABTE, KAHSAI

ART UNIT	PAPER NUMBER
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1624

MAIL DATE	DELIVERY MODE
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08/14/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/715,556

Applicant(s)

HOLDER ET AL.

Examiner

Kahsay Habte

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 July 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 26-29, 31 and 32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 29 is/are allowed.
- 6) ☒ Claim(s) 1-7, 26 and 27 is/are rejected.
- 7) ☒ Claim(s) 8, 28 and 31-32 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1-8, 26-29 and 31-32 are pending in this application.

Response to Amendment

2. Applicant's amendment filed 07/31/2007 in response to the previous Office Action (2/1/2007) is acknowledged. Rejection of claims 1-16 and 30 under 35 U.S.C. § 112, first paragraph (items 3 and 6) have been obviated. The prior art rejections under 102(a) and 103(a) have been maintained.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

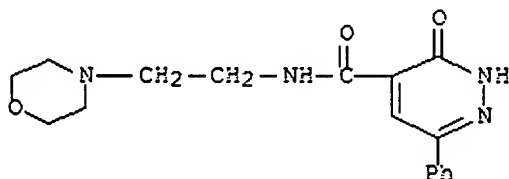
Claims 1-6 and 26-27 are rejected under 35 U.S.C. 102(a) as being anticipated by Nagato et al. WO 2002022587 A1. Cited reference at page 29 (first column, lines 7-8) teach a compound of interest: 2,3-dihydro-N-[2-(4-morpholinyl)ethyl]-3-oxo-6-phenyl-4-Pyridazinecarboxamide monohydrochloride that is the same as claimed compound when applicant's formula (I) has the following substituents:

A = CONH-CH₂-CH₂-morpholinyl (i.e. A = heterocycl-yl-CH₂-CH₂-) and Ar = phenyl. See below.

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RN 404933-59-1 CAPLUS

CN 4-Pyridazinecarboxamide, 2,3-dihydro-N-[2-(4-morpholinyl)ethyl]-3-oxo-6-phenyl-, monohydrochloride (9CI) (CA INDEX NAME)



● HCl

Applicants can overcome this rejection by providing an English translation of the foreign priority document.

Response to arguments

Applicant's argument filed 07/31/2007 has been fully considered but it is not persuasive.

Applicants argue that "Negtao do not include this particular compound, because in formula (1) of Negtao, A2 is 'aC3-8 cycloalkyl group, a c3-8 cycloalkenyl group, ...heterocyclic group' (i.e. A2 is not hydrogen). See U.S. Patent Application Publication No. 2003/0225081, which is an English-language publication of the U.S. national stage application of Negato, page 3, paragraphs [0011] and [0012]".

Upon further review of the search report and consultation with Chemical Abstract Services, the base compound with RN 404933-57-9 was found to be an index error. However, the hydrochloride salt (RN 404933-59-1) as shown above is disclosed in the experimental section as intermediate, see Example 12 of U.S. Patent Application

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Publication No. 2003/0225081 A1 at page 29 (first column, lines 7-8). Since applicants are claiming the salts of compounds of formula (I), the 102(a) rejection is proper.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

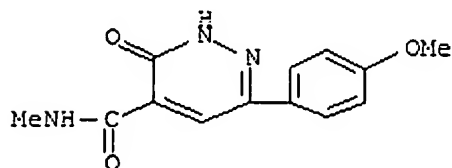
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-7 and 26-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoshizaki et al. (WO 99/44995). Cited reference discloses a compound of interest: 2,3-dihydro-6-(4-methoxyphenyl)-N-methyl-3-oxo-4-pyridazinecarboxamide that is almost the same as applicants when applicant's formula (I) has the following substituents:

Ar = phenyl substituted with methoxy; A = CONH-methyl (see below).

RN 243862-95-5 CAPLUS

CN 4-Pyridazinecarboxamide, 2,3-dihydro-6-(4-methoxyphenyl)-N-methyl-3-oxo-
(9CI) (CA INDEX NAME)



The only difference between applicant's compound and the prior art compound is the presence or absence of a methyl group on the phenyl ring. Applicant's compound is substituted by -OH on the phenyl group and the prior art compound is substituted by methoxy on the phenyl group. Compounds that differ only by the presence or absence of an extra methyl group or two are homologues. Homologues are of such close structural similarity that the disclosure of a compound renders *prima facie* obvious its homologue. The homolog is expected to be preparable by the same method and to have generally the same properties. This expectation is then deemed the motivation for preparing homologues. Of course, these presumptions are rebuttable by the showing of unexpected effects, but initially, the homolog are obvious even in the absence of a specific teaching to add or remove methyl groups. See *In re Wood*, 199 USPQ 137; *In re Hoke*, 195 USPQ 148; *In re Lohr*, 137 USPQ 548; *In re Magerlein*, 202 USPQ 473; *In re Wiechert*, 152 USPQ 249; *Ex parte Henkel*, 130 USPQ 474; *In re Fauque*, 121 USPQ 425; *In re Druey*, 138 USPQ 39. In all of these cases, the close structural similarity between two compounds differing by one or two methyl groups was itself sufficient show obviousness. See also MPEP 2144.09, second paragraph.

Response to arguments

Applicant's argument filed 07/31/2007 has been fully considered but it is not persuasive.

Applicants argue "[the] Examiner must first show that the prior art references teach or suggest all the claim limitations.....The supreme Court, in the recent *KSR* case, recognized that a showing of "teaching, suggestion, or motivation" could provide helpful insight in determining whether the claimed subject matter is obvious under Section

103(a)". The examiner disagrees with applicant's argument. Teaching, suggestion, or motivation (TSM) test are not the only rationale for making an obviousness rejection. Note that one should not conclude that an invention is unobvious simply because a rejection based on TSM cannot be made. The Supreme Court made a landmark patent decision recently (KSR case) when it handed down a ruling that could make it easier for the U.S. Patent Office to reject patents for obviousness. The "Teaching, Suggestion or Motivation" test, a standard by which the office judges the obviousness of a potential patent, is meant to be a general principle, not a rigid rule.

Applicants argue, "the Examiner has failed to show that Yoshiazki teaches or suggest all the limitations of the rejected claims". The examiner disagrees with applicant's arguments. See the above arguments and recent KSR case. The examiner is relying on legal precedent to reject the claims under 103(a).

According to MPEP 2144 and 2144.04 a legal precedent can be used as rationale for motivation. According to MPEP 2144.04, "if the facts in a prior legal decision are sufficiently similar to those in an application under examination, the examiner may use the rationale used by the court." In addition, according to MPEP 2144.08.II.A.4.(c) - "If such a species or subgenus is structurally similar to that claimed, its disclosure may motivate one of ordinary skill in the art to choose the claimed species or subgenus from the genus, based on the reasonable expectation that structurally similar species usually have similar properties. See, e.g., Dillon, 919 F.2d at 693, 696, 16 USPQ2d at 1901, 1904. See also Deuel, 51 F.3d at 1558, 34 USPQ2d at 1214 ('Structural relationships

may provide the requisite motivation or suggestion to modify known compounds to obtain new compounds. For example, a prior art compound may suggest its homologs because homologs often have similar properties and therefore chemists of ordinary skill would ordinarily contemplate making them to try to obtain compounds with improved properties."

As shown above, this is a homolog issue that is commonly raised in obviousness rejections. In order to overcome this rejection, applicants have to show unexpected results or amend the claim to overcome this rejection.

Allowable Subject Matter

5. Claim 29 is allowed.

Claim Objections

6. Claims 26-27 and 31-32 are objected to because of the following informalities: the recitation of "pharmaceutical preparation" appears to be defective. Claims 26-27 are drawn to "pharmaceutical composition" and not "pharmaceutical preparation", since there is no steps recited in preparing a composition.

Objection

7. Claims 8 and 28 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kahsay Habte whose telephone number is (571) 272-0667. The examiner can normally be reached on M-F (9.00AM- 5:30PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached at (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Kahsay Habte
Primary Examiner
Art Unit 1624

August 9, 2007